

AA Unit: 1645

Response to Arguments

11. The rejection of Claims 1, 5-8, 18 and 10-13, 15-17 under 35 U.S.C. § 112, first paragraph (Deposit), is traversed on the ground that mutant strains have been deposited that enable the claimed mutant strains, or the genes needed in the production of the mutant strains and are therefore enabled over the full scope of the claimed invention.

12. It is the position of the examiner that in light of the perfected Deposit requirement the instant specification has now enabled the sequence contained in the deposited strains/plasmids.

Amendment of the claims to recite the Deposited strains and the coding sequences contained therein could obviate this rejection.

13. The rejection of claims 1, 5-13, 15-18 under 35 U.S.C. 112, first paragraph (written description) is traversed by stating that "Applicants submit that is clear to one of ordinary skill in the art that sapB, sapC, sapD, sapE and sapF are not sapA homologs".

14. It is the position of the examiner that a surface associated protein (sap) evidences a conserved sequence for surface association, and a conserved sequence for expression through a Type I secretion system, thus defining the protein as a "sap" homolog. Dworkin et al (1995), teach sapB differs significantly from sapA only in the 5' region encoding the first 183 amino acids (see Dworkin et al, page 15097, col. 2, paragraph 1 and Figure 2 "hatched boxes show sapA and sapB region of coding identity). Evidence is provided in Dworkin et al that sapA and sapB are homologs of one another based upon conserved amino acid identities; additionally sap C,D, E and F are also homologs of sapA.

The acronyms assigned to the "homologs" do not define any specific chemical structure or biological function, but define them to evidence a conserved surface association (see Blaser et al, abstract B014, 1994) and a common mode of expression to the surface, thus defining the molecules to share homology as surface associated molecules.

Art Unit: 1645

Additionally, the term "homolog" is generally understood to define an evolutionary relatedness, and not to define any specific sequence or function. The now claimed genus of molecules contained or modified in mutant strains of *C.fetus* have not been so described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is the position of the examiner that while the Deposit has been made to enable a species of the now claimed genus of molecules, the claims are not limited to the Deposited strains and the genes contained therein; the genus has not been enabled over the full scope of the claims.

15. The rejection of claim 10 under 35 U.S.C. 112, first paragraph (written description) is traversed on the grounds that the claimed strain is a RecA mutant strain and a recA mutant of *C.fetus* strain has been deposited as PTA-4753.

16. It is the position of the examiner that claim 10 does not recite the deposited strain, and is directed to a genus of strains with any type of RecA mutation, and expresses any sapA homolog, the source and sequence of the sapA homolog not being limited to a *C.fetus* S-layer proteins. Amendment of claim 10 to recite the claim limitations utilized to traverse the rejection could obviate the rejection of the claim; Applicant's arguments are not commensurate in scope with the instantly claimed invention.

17. The rejection of claim 15 under 35 U.S.C. 112, first paragraph (written description) is traversed on the grounds that the claimed *E.coli* strain modified to express the surface array proteins C,D,E,F of *C.fetus* has been deposited as PTA-4750 and the plasmid in this strain can readily be used to construct the claimed bacterial strain.

18. It is the position of the examiner that claim 15 does not recite the deposited strain, and is directed to a genus of *E.coli* strains that comprise one of plurality of coding sequences from *C.fetus* that encode surface array proteins C,D,E and F but the instant specification has only

Art Unit: 1645

enabled a single species of the recited genus. Amendment of claim 15 to recite the claim limitations utilized to traverse the rejection could partially obviate the rejection of the claim, specifically amendment of claim 15 to be directed to the sequences contained in the deposited strain PTA-4750.

Additionally claim 16 depends from claim 15, and is directed to the expression of a chimeric protein that comprises a sapA homolog and the heterologous protein; the coding sequence for the sapA homolog coding sequence is not defined to be that of *C.fetus* but is any sapA coding sequence from any source. The genus of genes that encodes sapA set forth in claim 16 has not been described. Applicant's arguments are not commensurate in scope with the instantly claimed invention.

New Grounds of Objection/Rejection

Claim Objections

19. Claims 7, 12, 15, 16 and 17 are objected to because of the following informalities:

Cancelled
a. Claim 7 recites the phrase "said DNA cassette does not has a"; this phrase should recite the term --have-- rather than "has".

OK
b. Claim 12 recites the singular tense "strain", but refers back to a mixture of "strains"; the tense of the nouns is not consistent through out the claim.

OK
c. Claims 15 and 16 show a ". (period)" after the term "coli"; this is not the end of the sentence, nor is it an abbreviation. Removal of the period would place the claim in correct form.

OK
d. Claim 17, line 4 shows a ". (period)" after the word "coli", but also recites additional claim limitations following the period; removal of the period would place the claim in the correct format. Appropriate correction is required.